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EXAMINER	
SRIVASTAVA, KAILASH C	

ART UNIT	PAPER NUMBER
1655	

DATE MAILED: 07/13/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/695,762	MATSUNAGA, KENICHI	
	Examiner	Art Unit	
	Dr. Kailash C. Srivastava	1655	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *28 April 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-14* is/are pending in the application.

4a) Of the above claim(s) *3 and 6-14* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-2 and 4-5* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. Applicant's response filed 28 April 2006 to Office Action mailed 28 March 2006 is acknowledged and entered.

2. Claims 1-14 are pending.

Restriction/Election

3. Applicant's election with traverse of Group I, Claims 1-2, 4 and 5 filed 28 April 2006 to election requirement in Office Action mailed 28 March 2006 is acknowledged and entered. Applicant's traversal is on the ground (s) that restriction requirement in Office Action mailed 28 March 2006 should be withdrawn because inventions in groups I-III and V "do not constitute independent and distinct inventions and should be examined together"

Applicant's arguments have been fully and carefully considered, but are not found persuasive because of the reasons of record and for the reasons given below.

Contrary to applicant's contention, all of the claims encompassed in Groups I-III and V are distinct from each other in the components that each one of said inventive groups have and therefore each of the inventions encompassed in Groups I-III and V do not read on Group I invention that the applicant has elected for further prosecution. Inventive Groups II-III and V are drawn to compositions that despite being sub-combinations of Group I composition comprise different ingredients than those in Claims ascribed to Groups II-III and V. Inventive Groups II-III and V further differ from invention of Group I in functional effect and therefore follow typical US restriction practice. Additionally, each one of the inventions in Groups I-III and V belong to different Class and subclass (i.e., Classification). Moreover, the search for each of the distinct inventions of Groups I-III and V is not co-extensive particularly with regard to the literature search. For example the search strategy for the composition invention of Group I would require different key words than those required for the composition Claims in Groups II-III and V because as pointed above, despite having common components, the above-referred inventive composition Groups differ from each other in functional effects and steps of applying those compositions. For e.g., invention in Group II drawn to a composition comprising a microorganism strain would be limited only for that particular microorganism/strain, whereas search strategy for the invention in Group V composition for e.g., would require additional key words that distinguish the composition of Group V invention from Group II invention encompassing only the microorganisms/strain. Similarly, invention in Group III would require an entirely different search strategy than that required for the inventive Groups

I-II and V. Further, a reference that would anticipate the invention of one group would not necessarily anticipate or even make obvious another group. Moreover, the examination burden lies not only in the search of U.S. patents, burden also lies in the search for non-patent literature and foreign patents and examination of the claim language and specification for compliance with the statutes concerning new matter, distinctness and scope of enablement. Thus, clearly, different searches and issues are involved with each inventive group cited *supra*. Finally, the condition for patentability is different for each of the inventive Groups I-III and V. Thus, it will be an undue burden to examine all of the inventive Groups in one application. As to rejoining claims in Groups I, IV and VI, if the claims in Group I are found allowable, Examiner has already cited *In re Ochiae* in the Office Action mailed 30 September, 2004 informing the applicant to that effect and requirements thereof under the provisions of *In re Ochiae*. Therefore, the restriction requirement is still deemed proper and is made FINAL.

4. Accordingly, Claims 3 and 6-14 are withdrawn from further consideration as being directed to a non-elected invention. See 37 CFR §1.142(b) and MPEP § 821.03. Examiner suggests that the non-elected claims 2 and 6-14 cited above be canceled in response to this Office action to further expedite prosecution.

5. Claims 1-2 and 4-5 are examined on merits.

Priority

6. Applicant's claim for foreign priority under 35 U.S.C. §119 (a-d) to JAPAN 2002-381275 filed 27 December 2002 is acknowledged.

Objection To Specification

7. The specification is objected to because Line one of first page of specification, in its present form does not properly cite the application priority data. It is requested that the first line of the first page of the specification indicate that the instant application claims priority to a foreign Application, as follows:

"This application is claims priority under 35 U.S.C. §119 (a-d) to JAPAN 2002-381275 filed 27 December 2002"

8. 35 U.S.C. §112, first paragraph, requires the specification to be written in "full, clear, concise, and exact terms." The specification in its present form seems a literal translation of a foreign language document. Said specification is replete with terms, which are not clear, concise and exact. Said specification should be carefully revised in order to comply with 35 U.S.C. §112, first paragraph. Examples of some unclear, inexact or verbose terms used in the specification are: e.g., Page 1, line 6,

"prevent" and at Line 14, "then spat out"; at lines 26-27 misspelled "emitanine"; At page 2, Line 16, "obtainment". The examiner suggests that the applicants carefully revise the specification including the abstract to make the specification clearly comprehensible and in compliance with 35 U.S.C. §112, first paragraph. Applicant is warned to be careful to not add any new matter while revising the application for corrections to eliminate inexact or verbose terms to bring this application in compliance with 35 U.S.C. §112, first paragraph.

Examiner has not checked the entire specification to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification. Applicant is warned to be careful to not add any new matter while revising the application for corrections to eliminate any verbose or incorrect terms/language.

Claims Objection

9. Claims 2 and 4 are objected to for following reasons:

- In Claim 4 the phrase, "*Tricholoma matsutake* is dried powder of the mycelium of the FERM BP-7304 strain" is confusing because in Claim 2 the applicant claims that "*Tricholoma matsutake* is a broth, a "fruit body (including a spore) or a mycelium". Applicant needs to clearly define what the "*Tricholoma matsutake*"is? A basidiomycete fungus, an extract of "*Tricholoma matsutake*", a broth, a fruit body, a mycelium of a fungus or what?

Appropriate correction and definition is warranted in response to this Office Action.

Objection To Abstract

10. The abstract of the disclosure is objected to because said abstract:

- does not summarize the elected claimed invention in the proper language and format for an abstract of the disclosure.

  The abstract should be in narrative form and generally limited to a single paragraph on a separate sheet within the range of 50 to 150 words. It is important that the abstract not exceed 150 words in length since the space provided for the abstract on the computer tape used by the printer is limited. The form and legal phraseology often used in patent claims, such as "means" and "said," should be avoided. The abstract should describe the disclosure sufficiently to assist readers in deciding whether there is a need for consulting the full patent text for details.

  The language should be clear and concise and should not repeat information given in the title. It should avoid using phrases which can be implied, such as, "The disclosure concerns," "The disclosure defined by this invention," "The disclosure describes," etc.

Appropriate correction is required.

Claim Rejections - 35 U.S.C. § 102

11. The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

> ***A person shall be entitled to a patent unless –***
>
> ***(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.***
>
> ***(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.***

12. Claims 1-2 are rejected under 35 U.S.C. §102(b) as anticipated by Suzuki et al. (JP- 53006494, See English Abstract).

Claims recite a cancer preventive composition comprising *Tricholoma matsutake*, an extract thereof, a mycelium or a hot water extract thereof.

Suzuki et al. teach an anticancer composition comprising an extract of *Tricholoma matsutake,* a hot water extract of mycelium thereof, or of culture broth thereof (Abstract, Lines 1 and 21-29). Note that Suzuki et al. teach a composition comprising the same ingredient (s) and prepared according to the same steps, wherein said composition possesses the same properties (i.e., to ameliorate cancer) as instantly claimed. AN anti-cancer substance will inherently prevent or ameliorate a cancer depending upon the time of administering said composition to a person in need thereof.

Therefore, the reference is deemed to anticipate the cited claims.

13. Claims 1-2 are rejected under 35 U.S.C. §102(a) as anticipated by Sun (U.S. Patent Application Publication, US 2002/0127243 A1).

Claims recite a cancer preventive composition comprising *Tricholoma matsutake*, an extract thereof, a mycelium or a hot water extract thereof.

Sun teaches an anticancer composition (paragraph 7, Lines 5-7; Paragraph 18, Lines 6-12; Table 2; Paragraph 67, line 1 to Paragraph 68, Line 11 and Paragraph 101, Lines 1-1-3) comprising an extract of *Tricholoma matsutake,* or freeze-dried mushroom (Paragraph 7, Lines 5-9) Note that Sun teaches a composition comprising the same ingredient (s), wherein said composition possesses the same properties

(i.e., to ameliorate cancer) as instantly claimed. An anti-cancer substance will inherently prevent or ameliorate a cancer, metastasis or tumor, depending upon the time of administering said composition to a person in need thereof.

Therefore, the reference is deemed to anticipate the cited claims.

Claim Rejections - 35 U.S.C. § 103

14. The following is a quotation of 35 U.S.C. §103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> ***A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.***

15. Claims 1-2 and 4-5 are rejected under 35 U.S.C. § 103(a) as obvious over combined teachings from Suzuki et al. (JP- 53006494, See English Abstract) in view of Sun (U.S. Patent Application Publication, US 2002/0127243 A1).

Claims recite a cancer preventive composition comprising *Tricholoma matsutake*, an extract thereof, a mycelium or a hot water extract thereof. Claims further recite that said composition is dried powdered mycelium, or hot water or an alkaline solution extract of the mycelium of *Tricholoma matsutake* FERM BP-7304 strain.

Teachings from Suzuki et al. and Sun are discussed above.

It would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to modify Suzuki et al's teachings according to Sun's teachings to obtain a composition to administer to a person in need of to ameliorate or prevent cancer, because Suzuki et al teach an anti-cancer preparation prepared according to the same steps and employing same components and Sun teaches that a composition comprising a composition having its components powdered mushroom, wherein mushroom is *Tricholoma matsutake* ameliorates colon cancer when administered to a person in need thereof. The claimed invention and the cited prior art differ from each other only in the strain of *Tricholoma matsutake*. However, the adjustment of particular conventional working conditions (e.g., equivalent property having components in a composition) is deemed merely a matter of judicious selection and routine optimization of a result-effective parameter that is well within the purview of the skilled artisan

At the time, the claimed invention was made, an artisan of ordinary skill would have been motivated to combine the teachings from Suzuki et al. with beneficial teachings from Sun to obtain an anti-cancer composition comprising extracts of *Tricholoma matsutake*, or strain FERM BP-7304 strain as discussed *supra.*

From the teachings of the references cited *supra*, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

16. The prior art made of record and not relied upon is considered pertinent to Applicant's disclosure.

- Sun, A., U.S. Patent Application Publication US2003/0206923 A1. Issued 6 November 2003. Discusses composition comprising *Tricholoma matsutake* or powder made therefrom and application of said composition in dietary supplements and to treat colon cancer among other cancers.

Claim Rejections - 35 U.S.C. § 112

35 U.S.C. §112, First paragraph

17. The following is a quotation of the first paragraph of 35 U.S.C. § 112:

> ***The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.***

18. Claims 1-2 and 4-5 are rejected under 35 U.S.C.§112, first paragraph, because the specification, while enabling for a method to treat colon cancer (See Table 1 of the specification), does not reasonably provide enablement for a method to prevent colon cancer via instantly claimed method of administering the instantly claimed composition. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

From the record of the present written disclosure applicant has not clearly demonstrated that the administration of claimed composition inhibits colon cancer in the individual to whom the claimed composition has been administered. The data presented in Table 2 in support of applicant's claimed invention does not exhibit statistically significant differences among different experimental groups. Thus,

the example presented in the specification does not clearly demonstrate prevention of colon cancer via administering the claimed composition.

Inventions targeted for human therapy claiming prevention of a certain ailment bear a heavy responsibility to provide supporting evidence because of the unpredictability of the biological responses to therapeutic treatments. The standard of enablement is higher for such inventions because effective compositions to prevent claimed disease conditions are relatively rare, and may be unbelievable in the absence of supporting evidence. Claims drawn to pharmaceutically acceptable compositions and to methods of administering compounds to an individual that would in effect "prevent" the condition/ailment from happening require supporting evidence because of the unpredictability in biological responses to therapeutic treatments or therapeutic prophylaxis. In order to enable the skilled artisan to practice the invention as claimed, applicants would have to demonstrate the functional effect and describe the therapeutic effect or prophylactic effect, and describe the effective amounts of each ingredient of the composition for the administration of the composition intended for a method of therapeutic treatment or prophylaxis.

Accordingly, undue experimentation without a reasonable expectation of success as to how to determine which combination of claimed composition(s), or a "functional equivalent thereof" or "an active fragment thereof" in pharmaceutically acceptable carrier and in which therapeutic amounts of any or all of the claimed designated components would be effective in the instantly claimed method to administer the instantly claimed composition to obtain the instantly claimed functional effect of preventing colon cancer would be required to practice the invention as claimed due to the quantity of experimentation necessary; limited amount of guidance and limited number of working examples in the specification; nature of the invention; state of the prior art; relative skill level of those in the art; predictability or unpredictability in the art; and breadth of the claims. In re Wands, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988).

19. Claim 1-2 and 4-5 are rejected under 35 U.S.C. §112, first paragraph, because the specification, while describing that compositions comprising *Tricholoma matsutake*, or *Tricholoma matsutake*, FERM BP-7304 strain or extracts thereof or powdered preparations thereof, it does not provide any examples of obtaining said composition from any or every strain of *Tricholoma matsutake*. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims.

The fact that methods are known in the art to produce instantly composition from above-cited strain of *Tricholoma matsutake* would not allow one of ordinary skill in the art to extrapolate that

information to all strains of said organism and in the absence of evidence that the demonstrated composition is obtained from a particular strain, the claimed invention is not considered to be enabled.

An artisan in the art would not be able to practice the invention because an undue experimentation will be required to obtain the compounds cited *supra.* Undue experimentation would be required to practice the invention as claimed due to the quantity of experimentation necessary; limited amount of guidance and limited number of working examples in the specification; nature of the invention; state of the prior art; relative skill level of those in the art; predictability or unpredictability in the art; and breadth of the claims. *In re Wands*, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988).

20. Claims 1-2 and 4-5 are rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The claims are directed to *Tricholoma matsutake*, or *Tricholoma matsutake*, FERM BP-7304 strain that is the principle ingredient of the claimed "cancer preventive" composition.

21. The *Tricholoma matsutake*, or *Tricholoma matsutake*, FERM BP-7304 strain is essential to the invention recited in those claims. It must therefore be obtainable by a repeatable method set forth in the specification or otherwise be readily available to the public. If the microorganism (s) is not so obtainable or available, a deposit of the microorganism (s) in a recognized depository may satisfy the requirements of 35 U.S.C. §112.

In order to certify that the deposit meets the criteria set forth in 37 C.F.R. §§ 1.801-1.809, applicants may provide assurance of compliance by an affidavit or declaration, or by a statement by an attorney of record over his or her signature and registration number, showing that:

(a) during the pendency of this application, access to the invention will be afforded to the Commissioner upon request;

(b) all restrictions upon availability to the public will be irrevocably removed upon granting of the patent;

(c) the deposit will be maintained in a public depository for a period of 30 years or 5 years after the last request or for the effective life of the patent, whichever is longer; and

(d) the deposit will be replaced if it should ever become inviable.

Applicant is directed to 37 CFR §1.807 which states:

(b) A viability statement for each deposit of a biological material defined in paragraph (a) of this section not made under the Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the Purposes of Patent Procedure must be filed in the application and must contain:
(1) The name and address of the depository;
(2) The name and address of the depositor;
(3) The date of deposit;
(4) The identity of the deposit and the accession number given by the depository;
(5) The date of the viability test;
(6) The procedures used to obtain a sample if the test is not done by the depository; and
(7) A statement that the deposit is capable of reproduction.

Applicant is also directed to 37 CFR §1.809(d) which states:

(d) For each deposit made pursuant to these regulations, the specification shall contain:
(1) The accession number for the deposit;
(2) The date of the deposit.

35 U.S.C. §112, Second paragraph

22. The following is a quotation of the second paragraph of 35 U.S.C. § 112:

> ***The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.***

- Claim 1 is rendered vague and indefinite by the term "extract" because this term, in and of itself, does not adequately delineate its metes and bounds. This term is best defined as a product-by process since product-by-process claims are intended to define products that are otherwise difficult to define (and/or distinguish from the prior art). For example, is the extract obtained by extraction with water, a polar solvent, a non-polar solvent, an acid or base, a squeezed extract, or something else? In addition, from what part(s) of the microorganism is the extract obtained? It is well accepted in the herbal art that extraction with one of various distinct solvents, as well as from particular parts of therapeutic plants, has a profound impact on the final product with respect to the presence, absence, amounts, and/or ratios of active ingredients therein and, thud, its ability to provide the necessary functional effect(s) instantly claimed and/or disclosed. Since the extract itself is clearly essential to the claimed invention, the steps(s) by which the claimed extract is obtained are also clearly essential and, therefore, must be recited in the claim language itself (i.e., as a product-by-process). Note that although claims are interpreted in light of the specification, critical limitations from the specification cannot be

read into the claims (see, e.g., *In re* Van *Guens*, 988 F.2d 1181, 26 PSPG2d 1057 (DED. Cir. 1991). Accordingly, without the recitation of all these critical limitations as set forth above, the claims do not adequately define the instant invention.

- Claim 2 is rendered vague and indefinite by the use of parentheses. The use of parentheses encompassing terminology in the claims is indefinite because it is unclear if what is stated within the parentheses is a further limitation or simply alternative meaning.

- In Claims 4-5 each, the phrase "mycelium of the FERM BP-7304 strain" lacks sufficient antecedent basis because Claims 4-5 depend from Claim 1, however, in claim 1 there is no reference to said phrase. Appropriate correction required.

All other claims depend directly or indirectly from the rejected claims (e.g., Claim 1) and are, therefore, also rejected under 35 U.S.C. §112, second paragraph for the reasons set forth above.

Conclusion

23. For aforementioned reasons, no Claims are allowed.

24. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Kailash C. Srivastava whose telephone number is (571) 272-0923. The examiner can normally be reached on Monday to Thursday from 7:30 A.M. to 6:00 P.M. (Eastern Standard or Daylight Savings Time).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Terry McKelvey, can be reached on (571)-272-0775 Monday through Friday 8:30 A.M. to 5:00 P.M. The fax phone number for the organization where this application or proceeding is assigned is (571)-273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding may be obtained from the Patent Application Information Retrieval (i.e., PAIR) system. Status information for the published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (i.e., EBC) at: (866)-217-9197 (toll-free). Alternatively, status inquiries should be directed to the receptionist whose telephone number is (703) 308-0196.

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July 6, 2006

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